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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/406,832 | 09/28/1999 | KEIKO YUGAWA | 43888-067 | 1982 |

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WASHINGTON, DC 20005-3096

EXAMINER

NOGUEROLA, ALEXANDER STEPHAN

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| ART UNIT | PAPER NUMBER |
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1743

DATE MAILED: 12/03/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|-----------------|---------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 09/406,832 | YUGAWA ET AL. | |
| | Examiner | Art Unit | |
| | ALEX NOGUEROLA | 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on 16 August 2001 and 17 September 2001.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 5-81 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☒ Claim(s) 5-20, 22-29 and 35-37 is/are allowed.

6) ☒ Claim(s) 21, 30-34, 38, 47-51, 55, 59-65, 68-74 and 77-81 is/are rejected.

7) ☒ Claim(s) 39-46, 52-54, 56-58, 66, 67, 75, 76 is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☒ All b) ☐ Some * c) ☐ None of:

1. ☒ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. _____.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.

4) ☐ Interview Summary (PTO-413) Paper No(s). _____

5) ☐ Notice of Informal Patent Application (PTO-152)

6) ☐ Other: _____

Allowable Subject Matter

1. Prosecution on the merits of this application is reopened. The examiner received applicant's Supplemental Amendment of September 17, 2001 after the mailing of the Notice of Allowance on September 24, 2001. Thus it had not been considered before preparing the Notice of Allowance. Claims 5-20, which were indicated to be allowable, are still allowed; however, several of the new claims 21-81, which were added by the Supplemental Amendment, are rejected.

2. Applicant is advised that the Notice of Allowance mailed September 24, 2001 is vacated. If the issue fee has already been paid, applicant may request a refund or request that the fee be credited to a deposit account. However, applicant may wait until the application is either found allowable or held abandoned. If allowed, upon receipt of a new Notice of Allowance, applicant may request that the previously submitted issue fee be applied. If abandoned, applicant may request refund or credit to a Deposit Account.

Claim Rejections - 35 USC § 112

3. Claims 30-34, 47-51, 59-63, 68-72, 77-81 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention:

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a) Claim 31: a step appears to be missing. If the reagent composition is to be used to assay glucose and the reagent composition includes a glucose enzyme, how will the reagent composition be prevented from reacting with glucose that is used as a stabilizer.

b) Claims 30-34, 59-63, 68-72, 77-81 what is the scope of "a derivative thereof"?

Note that dependent claims will have the deficiencies of base and intervening claims.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

5. Claims 21, 38, 64, and 73 are rejected under 35 U.S.C. 102(b) as being anticipated by newly cited JAPIO abstract of Adachi et al. (JP 409140378 A).

Addressing Claim 21, Adachi et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein calcium citrate has been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. See the abstract and col. 6, ll. 7-49. Adachi et al. do not mention that calcium citrate stabilizes the glucose dehydrogenase; however,

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this property is anticipated because it is inherent to citric acid when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline.

Note that applicant's Claim 21 only has one step, adding calcium citrate to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Addressing Claim 38, Adachi et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein a citrate, calcium citrate, has been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Adachi et al. do not mention that the citrate stabilizes the glucose dehydrogenase; however, this property is anticipated because it is inherent to citrate when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline: 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Addressing Claim 64, Adachi et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein a glutamic acid (an organic acid) and citric acid have been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Adachi et al. do not mention that the glutamic acid stabilizes the glucose dehydrogenase and that citric acid is a buffer; however, these priorities are anticipated because they are inherent in these compounds when

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used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Note that applicant is only combining these compounds with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline, as does Adachi et al. So, if Adachi et al. teach the same steps as applicant claims then the properties of the resulting composition must be the same. Namely that it will be stabilized. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Addressing Claim 73, Adachi et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein a glutamic acid (an organic acid) and citric acid have been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Adachi et al. do not mention that the glutamic acid stabilizes the glucose dehydrogenase and that citric acid is a buffer; however, these priorities are anticipated because they are inherent in these compounds when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Note that applicant is only combining these compounds with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline, as does Adachi et al. So, if Adachi et al. teaches the same composition as applicant claims then the properties of the compositions must be the same. Namely that they will be stabilized. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

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6. Claims 21, 38, 64, 65, 73, and 74 are rejected under 35 U.S.C. 102(e) as being anticipated by newly cited Vetter et al. (US 6,025,203).

Addressing Claim 21, Vetter et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein citric acid has been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. See the abstract and col. 6, ll. 7-49. Vetter et al. do not mention that citric acid stabilizes the glucose dehydrogenase; however, this property is anticipated because it is inherent to citric acid when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline.

Note that applicant's Claim 21 only has one step, adding citric acid to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Addressing Claim 38, Vetter et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein citric acid has been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. See the abstract and col. 6, ll. 7-49. Vetter et al. do not mention that citric acid stabilizes the glucose dehydrogenase; however, this property is anticipated because it is inherent to citric acid when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline: 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

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Addressing Claims 64 and 65; Vetter et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein calcium chloride and citric acid have been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. See the abstract and col. 6, ll. 7-49. Vetter et al. do not mention that the calcium acid stabilizes the glucose dehydrogenase and that citric acid is a buffer; however, these properties are anticipated because they are inherent in these compounds when used in combination with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. Note that applicant is only combining these compounds with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline, as does Vetter et al. So, if Vetter et al. teach the same steps as applicant claims then the properties of the resulting composition must be the same. Namely that it will be stabilized. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Addressing Claims 73 and 74; Vetter et al. teach a glucose dehydrogenase reagent composition for use in a glucose sensor wherein calcium chloride and citric acid have been added to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline. See the abstract and col. 6, ll. 7-49. Vetter et al. do not mention that the calcium acid stabilizes the glucose dehydrogenase and that citric acid is a buffer; however, these properties are anticipated because they are inherent in these compounds when used in combination with glucose dehydrogenase

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whose coenzyme is pyrrolo-quinoline. Note that applicant is only combining these compounds with glucose dehydrogenase whose coenzyme is pyrrolo-quinoline, as does Vetter et al. So, if Vetter et al. teach the same composition as applicant claims then the properties of the compositions must be the same. Namely that they will be stabilized. 'The claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 55, 59-62, 64, 68-73, 77-81 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crismore et al. (US 5,997,817) in view of newly cited Vetter et al. (US 6,025,203) and newly cited Gotoh et al. (US 6,071,391).

Addressing Claims 55 and 59-62; Crismore et al. teach a glucose sensor comprising an electrically insulating base plate, an electrode system including at least a working electrode and a counter electrode formed on the base plate, and a reaction layer which is formed in contact with or in the vicinity of the electrode system wherein the reaction layer contains a sugar (trehalose); a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline; and a buffer (sodium succinate is

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implied to be a buffer in col. 6, ll. 41-46). See col. 5, ll. 60-67; col. 6, ll. 41-46; and col. 7, ll. 45-59. Sodium succinate is not in applicant's list of buffers in Claim 55. Vetter et al. teach a reagent layer comprising a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline and citric acid, which applicant claims as a buffer. Citric acid buffers at pH 5.0 (Gotoh et al. col. 8, ll. 46-50) and sodium succinate buffers at pH "approximately 6.76 plus or minus 0.05" (Crismore et al. col. 6, ll. 41-46). So, barring evidence to the contrary, such as unexpected results, the choice of buffer is just a matter of optimizing the pH for the sample. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use citric acid as taught by Gotoh et al. in the invention of Crismore et al. because this will buffer the pH at 5.0, which will be optimal for some samples.

For Claim 60, note that as shown by the CAPLUS abstract of Takahasi et al. ("Effect of a trehalose inhibitor, validoxylamine A, on three species of flies", *Appl. Entomol. Zool.* (1995), 30(1), 231-9), trehalose can be derivatized from glucose.

For Claims 62 and 63, note that as implied by the CAPLUS abstract of Cucinotta et al. (Three-dimensional cyclodextrin: a new class of hosts by trehalose capping of B-cyclodextrin", *J. Inclusion Phenom. Mol. Recognit. Chem.* (1996), 25(1-3), 39-42) trehalose can be synthesized from a dextrin derivative.

Addressing Claims 64 and 68-72; Crismore et al. teach a glucose dehydrogenase composition from by adding to glucose dehydrogenase whose coenzyme is pyrrolo-quinoline a sugar (trehalose) and a buffer (sodium succinate is implied to be a buffer in col. 6, ll. 41-46). See col. 5, ll. 60-67; col. 6, ll. 41-46; and col. 7, ll. 45-59. Sodium succinate is not in applicant's

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list of buffers in Claim 64. Vetter et al. teach a reagent layer comprising a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline and citric acid, which applicant claims as a buffer. Citric acid buffers at pH 5.0 (Gotoh et al. col. 8, ll. 46-50) and sodium succinate buffers at pH "approximately 6.76 plus or minus 0.05" (Crismore et al. col. 6, ll. 41-46). So, barring evidence to the contrary, such as unexpected results, the choice of buffer is just a matter of the optimizing the pH for the sample. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use citric acid as taught by Gotoh et al. in the invention of Crismore et al. because this will buffer the pH at 5.0, which will be optimal for some samples.

As for trehalose being a stabilizer it should be noted that "[t]he claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977)." See MPEP 2112.

For Claim 69, note that as shown by the CAPLUS abstract of Takahasi et al. ("Effect of a trehalose inhibitor, validoxylamine A, on three species of flies", Appl. Entomol. Zool. (1995), 30(1), 231-9), trehalose can be derivatized from glucose.

For Claims 71 and 72, note that as implied by the CAPLUS abstract of Cucinotta et al. (Three-dimensional cyclodextrin: a new class of hosts by trehalose capping of B-cyclodextrin", J. Inclusion Phenom. Mol. Recognit. Chem. (1996), 25(1-3), 39-42) trehalose can be synthesized from a dextrin derivative.

Addressing Claims 73, 77-81; Crismore et al. teach a glucose dehydrogenase composition comprising glucose dehydrogenase whose coenzyme is pyrrolo-quinoline, a sugar (trehalose),

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and a buffer (sodium succinate is implied to be a buffer in col. 6, ll. 41-46). See col. 5, ll. 60-67; col. 6, ll. 41-46; and col. 7, ll. 45-59. Sodium succinate is not in applicant's list of buffers in Claim 73. Vetter et al. teach a reagent layer comprising a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline and citric acid, which applicant claims as a buffer. Citric acid buffers at pH 5.0 (Gotoh et al. col. 8, ll. 46-50) and sodium succinate buffers at pH "approximately 6.76 plus or minus 0.05" (Crismore et al. col. 6, ll. 41-46). So, barring evidence to the contrary, such as unexpected results, the choice of buffer is just a matter of the optimizing the pH for the sample. It would have been obvious to one with ordinary skill in the art at the time the invention was made to use citric acid as taught by Gotoh et al. in the invention of Crismore et al. because this will buffer the pH at 5.0, which will be optimal for some samples.

As for trehalose being a stabilizer it should be noted that '[t]he claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).' See MPEP 2112.

For Claim 78, note that as shown by the CAPLUS abstract of Takahasi et al. ("Effect of a trehalose inhibitor, validoxylamine A, on three species of flies", Appl. Entomol. Zool. (1995), 30(1), 231-9), trehalose can be derivatized from glucose.

For Claims 80 and 81, note that as implied by the CAPLUS abstract of Cucinotta et al. (Three-dimensional cyclodextrin: a new class of hosts by trehalose capping of B-cyclodextrin", J. Inclusion Phenom. Mol. Recognit. Chem. (1996), 25(1-3), 39-42) trehalose can be synthesized from a dextrin derivative.

Allowable Subject Matter

9. Claims 5-20, 22-29, and 35-37 are allowed.
10. Claim 39-46, 52-54, 56-58, 66, 67, 75, and 76 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
11. Claims 30-34 and 47-51 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.
12. The following is a statement of reasons for the indication of allowable subject matter:
 - a) Claims 5, 22, and 39: the cited prior art does not teach phthalic acid or a phthalate in a reaction layer with a glucose dehydrogenase whose coenzyme is pyrrolo-quinoline;
 - b) Claims 6-20 depend directly or indirectly from Claim 5;
 - c) Claims 23-37 depend directly or indirectly from Claim 22;
 - d) Claims 40-54 depend directly or indirectly from Claim 39;
 - e) Claims 56-58 each teach closed lists of compounds that are not taught in the prior art of record as ingredients in the reaction layer of Claim 55;
 - f) Claims 66 and 67 each teach closed lists of compounds that are not taught in the prior art of record as ingredients in the reaction layer of Claim 64; and

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g) Claims 75 and 76 each teach closed lists of compounds that are not taught in the prior art of record as ingredients in the reaction layer of Claim 73.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (703) 305-5686. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JILL WARDEN can be reached on (703) 308-4037. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-7719 for regular communications and (703) 305-5433 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1193.

Alex Noguerola
November 13, 2001


Jill Warden
Supervisory Patent Examiner
Technology Center 1700